US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2017 (FY17) PEER REVIEWED MEDICAL RESEARCH PROGRAM (PRMRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY17 PRMRP called for applications in response to program announcements (PAs) for three award mechanisms released in May 2017:

- Focused Program Award
- Investigator-Initiated Research Award
- Technology/Therapeutic Development Award

Pre-applications were received for these three PAs in July 2017 and screened in August 2017 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these three PAs in October 2017 and peer reviewed in December 2017. Programmatic review was conducted in February 2018.

In response to the Focused Program Award PA, 128 pre-applications were received and the PIs of 34 of these were invited to submit a full application. Thirty-one (31) compliant applications were received and 3 (9.7%) were recommended for funding for a total of $29.6M.

In response to the Investigator-Initiated Research Award PA, 851 pre-applications were received and the PIs of 417 of these were invited to submit a full application. The Investigator-Initiated Research Award includes a Partnering PI Option, for which two applications were submitted by partnered PIs for conduct of a single research project. Two hundred forty-seven (247) compliant traditional Investigator-Initiated Research Award applications were received and 26 (10.5%) were recommended for funding for a total of $43.4M. Three hundred four (304) compliant Investigator-Initiated Research Award with Partnering PI Option applications were received, representing 152 projects, and 42 (21 projects, 13.8%) were recommended for funding for a total of $48.0M.

In response to the Technology/Therapeutic Development Award PA, 302 pre-applications were received and the PIs of 129 of these were invited to submit a full application. One hundred twenty-two (122) compliant applications were received and 20 (16.4%) were recommended for funding for a total of $73.1M.

Submission and award data for the FY17 PRMRP are summarized in the tables below.

Table 1. Submission/Award Data for the FY17 PRMRP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Focused Program Award	128	34 (27%)	31	3 (9.7%)	$29,578,381
Investigator-Initiated Research Award†	851	417 (49%)	409	47 (11.5%)	$91,427,779
Technology/ Therapeutic Development Award	302	129 (43%)	122	20 (16.4%)	$73,050,373
Total	**1,281**	**580 (45%)**	**562**	**70 (12.5%)**	**$194,056,533**

*These data reflect funding recommendations only. Pending FY17 award negotiations, final numbers will be available after September 30, 2018.

†The data in this row represent the total number of individual projects, but the total funds in the final column represent the budget for all individual applications.

Table 2. FY17 PRMRP Application Data by Topic Area*

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Acute Lung Injury	34	4 (12%)	$11,160,967
Antimicrobial Resistance	54	6 (11%)	$15,022,533
Arthritis	6	0 (0%)	$0
Burn Pit Exposure	2	0 (0%)	$0
Chronic Migraine and Post-Traumatic Headache	7	2 (29%)	$4,192,500
Congenital Heart Disease	28	3 (11%)	$7,694,597
Constrictive Bronchiolitis	3	0 (0%)	$0
Diabetes	50	3 (6%)	$7,005,571
Diarrheal Diseases	12	0 (0%)	$0
Dystonia	4	1 (25%)	$1,493,248
Early Trauma Thermal Regulation	1	0 (0%)	$0
Eating Disorders	9	1 (11%)	$2,089,392
Emerging Infectious Diseases	27	1 (4%)	$1,902,000
Epidermolysis Bullosa	6	4 (67%)	$9,290,107
Focal Segmental Glomerulosclerosis	7	0 (0%)	$0
Fragile X Syndrome	3	1 (33%)	$1,400,559
Guillain-Barré Syndrome	3	1 (33%)	$1,760,256
Hepatitis B and C	6	2 (33%)	$3,108,308
Hereditary Angioedema	0	0 (0%)	$0
Hydrocephalus	4	1 (25%)	$2,338,656

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Immunomonitoring of Intestinal Transplants	1	0 (0%)	$0
Inflammatory Bowel Diseases	21	0 (0%)	$0
Influenza	16	2 (13%)	$9,752,206
Integrative Medicine	0	0 (0%)	$0
Interstitial Cystitis	6	1 (17%)	$3,290,595
Malaria	24	2 (8%)	$5,028,546
Metals Toxicology	11	0 (0%)	$0
Mitochondrial Disease	15	2 (13%)	$5,406,955
Musculoskeletal Disorders	12	1 (8%)	$961,764
Nanomaterials for Bone Regeneration	18	2 (11%)	$7,503,005
Non-Opioid Pain Management	13	3 (23%)	$7,910,694
Pancreatitis	3	0 (0%)	$0
Pathogen-Inactivated Dried Cryoprecipitate	0	0 (0%)	$0
Polycystic Kidney Disease	7	2 (29%)	$3,567,750
Post-Traumatic Osteoarthritis	26	6 (23%)	$29,130,023
Pulmonary Fibrosis	16	2 (13%)	$4,914,946
Respiratory Health	13	2 (15%)	$11,891,999
Rett Syndrome	4	0 (0%)	$0
Rheumatoid Arthritis	8	1 (13%)	$1,816,920
Scleroderma	7	1 (14%)	$2,350,500
Sleep Disorders	14	2 (14%)	$4,381,222
Spinal Muscular Atrophy	4	1 (25%)	$2,707,800
Sustained-Release Drug Delivery	2	1 (50%)	$2,994,843
Tinnitus	2	1 (50%)	$4,086,335
Tuberculosis	11	2 (18%)	$4,722,718
Vaccine Development for Infectious Disease	25	2 (8%)	$5,572,493
Vascular Malformations	8	1 (13%)	$2,351,667
Women's Heart Disease	9	3 (33%)	$5,254,858
Total	**562**	**70 (12.4%)**	**$194,056,533**

*Data in this table represent the total number of individual projects submitted, but the total funds in the final column represent the budget for all individual applications.

THE TWO-TIER REVIEW SYSTEM

The USAMRMC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) of the National Academy of Sciences report, Strategies for Managing the Breast Cancer Research Program: A Report to the Army Medical Research and Development Command. The IOM report recommended a two-tier review process and concluded that the best course would be to establish a peer review system that reflects not only the traditional strengths

of existing peer review systems, but also is tailored to accommodate program goals. The Command has adhered to this proven approach for evaluating competitive applications. An application must be favorably reviewed by both levels of the two-tier review system to be funded.

THE FIRST TIER—Scientific Peer Review

Peer review for applications received in response to these three PAs was conducted in December 2017 by review panels based on the evaluation criteria specified in each respective PA. Each peer review panel included a Chair, scientific reviewers, consumer reviewers, and a nonvoting Scientific Review Officer (SRO). Investigator-Initiated Research Award and Technology/Therapeutic Development Award applications were peer reviewed by 26 panels and Focused Program Award applications were peer reviewed by 15 panels.

Individual Peer Review Panels

The Chair for each panel presided over the deliberations. Applications were discussed individually. The Chair called upon the assigned reviewers for an assessment of the merits of each application using the evaluation criteria published in the appropriate PA. Following a panel discussion, the Chair summarized the strengths and weaknesses of each application, and panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores: Panel members were asked to rate each peer review evaluation criterion as published in the appropriate PA. A scale of 1 to 10 was used, with 1 representing the lowest merit and 10 the highest merit, using whole numbers only. The main reasons for obtaining the criteria ratings were to (1) place emphasis on the published evaluation criteria and provide guidance to reviewers in determining an appropriate overall score, and (2) provide the applicant, the Programmatic Panel, and the Command with an informed measure of the quality regarding the strengths and weaknesses of each application. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global or percentile scores.

Overall Score: To obtain an overall score, a range of 1.0 to 5.0 was used (1.0 representing the highest merit and 5.0 the lowest merit). Reviewer scoring was permitted in 0.1 increments. Panel member scores were averaged and rounded to arrive at a two-digit number (1.2, 1.9, 2.7, etc.). The following adjectival equivalents were used to guide reviewers: Outstanding (1.0–1.5), Excellent (1.6–2.0), Good (2.1–2.5), Fair (2.6–3.5), and Deficient (3.6–5.0).

Summary Statements: The Scientific Review Officer on each panel was responsible for preparing a Summary Statement reporting the results of the peer review for each application. The Summary Statements included the applicants' abstracts, impact and military relevance statements, the evaluation criteria and overall scores, peer reviewers' written comments, and the essence of panel discussions. This document was used to report the peer review results to the Programmatic Panel. It is the policy of the USAMRMC to make Summary Statements available to each applicant when the review process has been completed.

THE SECOND TIER—Programmatic Review

Programmatic review was conducted in February 2018, by the FY17 Programmatic Panel that was comprised of representatives of each branch of the military Services, the Department of Veterans Affairs, the Office of the Assistant Secretary of Defense for Health Affairs, the Department of Health and Human Services, and ad hoc reviewers. Programmatic review is a comparison-based process that considers scientific evaluations across all disciplines and specialty areas. Programmatic Panel members do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully scrutinize applications to allocate the limited funds available to support each of the award mechanisms as wisely as possible. Programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; adherence to the intent of the award mechanism; military relevance; program portfolio composition; and relative impact. After programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency J9, Research and Development Directorate approved funding for the applications recommended during programmatic review.